



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent application of:

William Crismore et al.

Serial No. 10/008,788

Filed: December 7, 2001

ELECTROCHEMICAL  
BIOSENSOR TEST STRIP

Before the Examiner Lyle Alexander  
Group Art Unit 1743

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Commissioner for Patents, P. O. Box 1450,  
Alexandria, VA 22313-1450 on

March 8, 2007

Thomas Q. Henry  
Name of Registered Representative

Thomas Q. Henry  
Signature

March 8, 2007  
Date of Signature

03/13/2007 SSESHE1 00000003 10008788

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**FOURTH SUPPLEMENTAL  
INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure embodied in 37 C.F.R.1.56, Applicant wishes to bring to the attention of the Examiner the following patents, publications and/or other information listed on the enclosed PTO Form PTO/SB-08A and/or PTO/SB-08B. This information has not been previously submitted in this application, and has not been heretofore cited by the Examiner. Copies of cited items are enclosed in accordance with 37 C.F.R. § 1.98.

In addition to other art identified herein, applicant has determined that a prior art device marketed by Bayer Corporation under the trademark GLUCOMETER ELITE® was being sold more than a year before the earliest priority date for this application, and therefore constitutes prior art under §102(b). Below is a picture of the Glucometer Elite product, and an actual sample of the device is attached hereto on the right side of the below picture. Also

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SB/17 (01-00)

Approved for use through 07/31/2006. OMB 0651-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE  
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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2006****Complete if Known**

Application Number	10/008,788
Filing Date	November 7, 2001
First Named Inventor	William CRISMORE
Examiner Name	Lyle Alexander
Art Unit	1743
Attorney Docket No.	7404-436

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$180)

**METHOD OF PAYMENT (check all that apply)**

- ☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_
- ☒ Deposit Account Deposit Account number: 23-3030 Deposit Account Name: Woodard, Emhardt, Moriarty, McNett & Henry LLP  
For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)
- ☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee
- ☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments.

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity	Fee (\$)	Small Entity	Fee (\$)	Small Entity	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)  
Each independent claim over 3 (including Reissues)  
Multiple dependent claims

Fee (\$)	Small Entity
50	25
200	100
360	180

**Multiple Dependent Claims**

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Fee (\$)	Fee Paid (\$)
-20 or HP	=-20	x	=0	x	=0

HP = highest number of total claims paid for, if greater than 20

Independent Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
-3 or HP	=-3	x	=0

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 C.F.R. 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
-100	=	/50 = (round up to a whole number)	x	0

**4. OTHER FEE(S)**

Information Disclosure Statement (37 C.F.R. 1.17(p))

Fee Paid (\$)  
180**SUBMITTED BY**

Signature	<i>Thomas Q. Henry</i>	Registration No. (Attorney/Agent)	28,309	Telephone	(317) 634-3456
Name (Print/Type)	Thomas Q. Henry	Date	March 8, 2007		

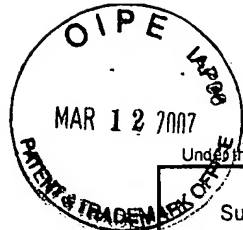
**CERTIFICATE OF MAILING OR TRANSMISSION**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

Name (Print/Type)	GAIL MERCER
Signature	<i>Gail Mercer</i>
Date	March 8, 2007

#393694

WEMMH #393694



Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/008,788
Filing Date	December 7, 2001
First Named Inventor	William Crismore
Art Unit	1743
Examiner Name	Lyle Alexander
Attorney Docket No.	7404-436

Sheet	1	of	2
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**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (If known)			
		US- 4,432,366	02/21/1984	Margules et al.	
		US- 5,304,468	04/19/1994	Phillips et al.	
		US- 5,320,732	06/14/1994	Nankai et al.	
		US- 5,395,504	03/07/1995	Saurer et al.	
		US- 5,407,554	04/18/1995	Suarer et al.	
		US- 5,547,702	08/20/1996	Gleisner et al.	
		US- 5,563,042	10/08/1996	Phillips et al.	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
		CN 1146016	03/26/1997	Panasonic Corporation		<input type="checkbox"/>
		JP 5164756	6/29/1993	Rohto Pharmaceutical Co.		<input type="checkbox"/>
		EP 0 407 800 A	01/16/199	Miles Inc.		<input type="checkbox"/>
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Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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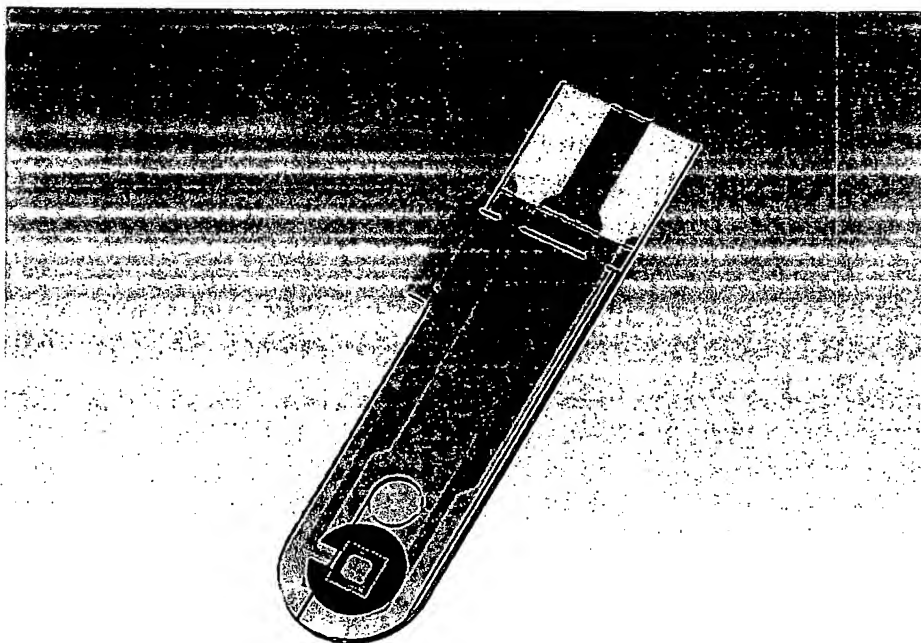
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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/008,788
				Filing Date	December 7, 2001
				First Named Inventor	William Crismore
				Art Unit	1743
				Examiner Name	Lyle Alexancer
Sheet	2	of	2	Attorney Docket No.	7404-436

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T <sup>6</sup>
		Glucometer Elite product and package insert	<input type="checkbox"/>
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Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional).  
<sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.



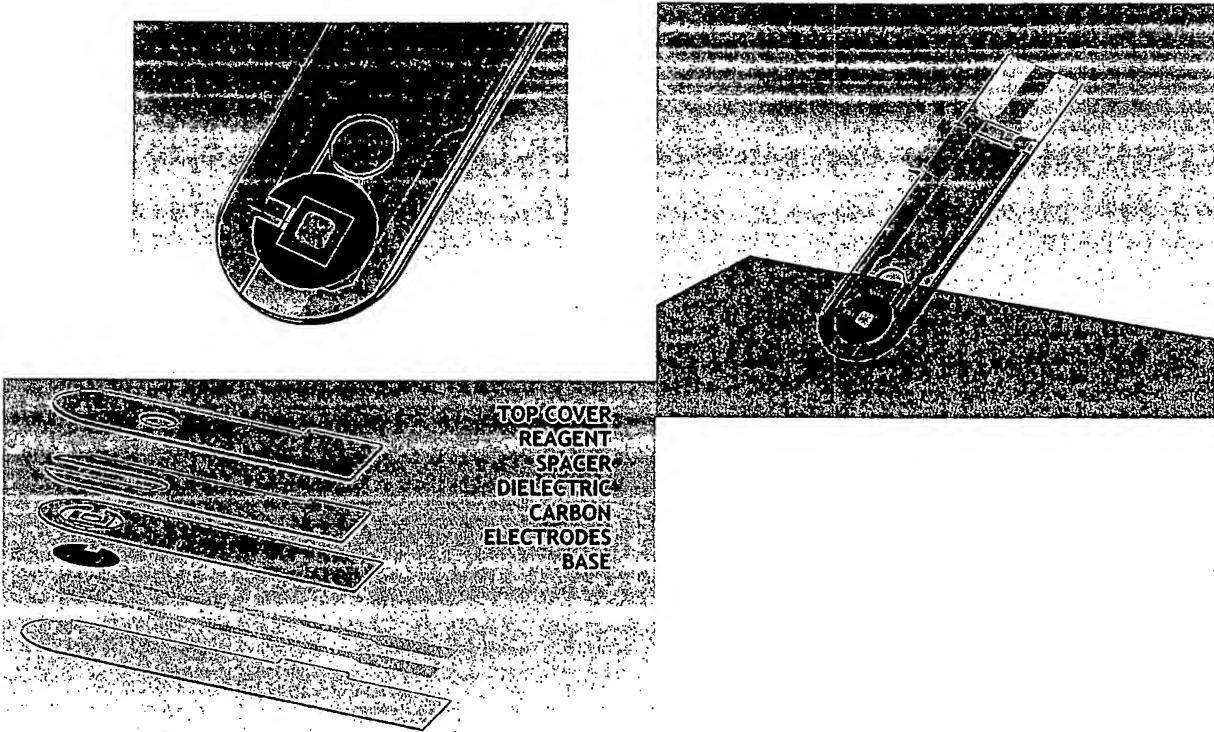
presented on the following page are additional views of the Elite product, including an exploded view showing what are believed to be 7 distinct components of the strip.

Applicant submits these materials in a good faith effort to enable the patent examiner to understand the construction of the Glucometer Elite product, and applicant believes the depictions to be accurate. If there are differences between these depictions and the actual Glucometer Elite device, it is believed that they would not exist as to issues relating to consideration of the Glucometer Elite device as prior art to the present invention, as further explained below.

The Glucometer Elite product is an electrochemical test strip including a pair of electrodes received at the interior end of a capillary channel. The channel extends inwardly from a sample application port at the perimetric edge of the test strip. The Glucometer Elite device includes several layers, including a spacer and a top cover. It appears clear that the

spacer and top cover are

## GLUCOMETER ELITE



both transparent materials, as the components underneath these layers are visible. For example, the electrodes, the carbon layer, and the dielectric (which shields portions of the electrodes from the capillary channel) are all located below the spacer, and yet all are visible in the assembled test strip.

To the extent that the Glucometer Elite product includes opacity, it is in components that lay below the spacer which defines the capillary channel. More importantly, there is nothing in the Glucometer Elite test strip which comprises opaque portions or colored portions which distinguish the capillary fill channel from other parts of the test strip. Thus, when blood is dosed to the Glucometer Elite strip, the user would be able to see blood moving into the strip, but would not be able to tell if it was filling the capillary channel or some lesser portion of the interior of the strip.

The Glucometer Elite test strip fails to provide opaque and/or colored portions which define a viewing area that confirms sufficient filling of the test strip when that viewing area has been filled with the blood sample. The opaque portions of the Glucometer Elite strip are not aligned with the sides of the capillary.

Applicant is also re-submitting prior art previously submitted in Applicant's Second Supplemental Information Disclosure Statement filed November 29, 2005. In said Second Supplemental Information Disclosure Statement, Applicant incorrectly stated that the Statement was being submitted before the first Office Action on the Merits. This was an erroneous statement (three Office Actions had been issued in the application), occurred as a result of a clerical error and was made without deceptive intent. It is noted that the second reason given in the Second Supplemental Information Disclosure Statement for no fee being due (that the references were first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior) was accurate. Applicant is therefore re-submitting the references from the Second Supplemental Information Disclosure Statement in order to correct the record regarding the unintentional misstatement.

Applicant is also re-submitting prior art previously submitted in Applicant's Third Supplemental Information Disclosure Statement filed April 7, 2006. In said Third Supplemental Information Disclosure Statement, Applicant incorrectly stated that the Statement was being submitted before the first Office Action on the Merits. This was an erroneous statement (three Office Action had been issued in the application), occurred as a result of a clerical error and was made without deceptive intent. Applicant is therefore re-submitting the references from the Third Supplemental Information Disclosure Statement in order to correct the record regarding the unintentional misstatement and to pay the fee required under 37 C.F.R. §1.17(p).

The identified information, taken alone or in combination with other art, provides information relating to the subject matter of the invention, but fails to teach, disclose or suggest the present invention. The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b).

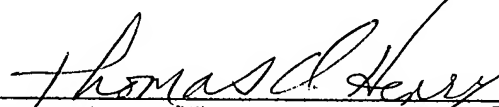
This Statement is being submitted more than three months after the filing date of the application and after the mailing of the first Office Action on the merits, but before the mailing of a final action under § 1.113 or a Notice of Allowance under S 1.311.

It is respectfully submitted that, because prosecution of the present application on the merits has not yet been closed, the information submitted herewith must be considered by the Examiner. *See* 37 C.F.R. §1.97 and MPEP §609.04(b)(II).

In accordance with § 1.97(c), the Commissioner is authorized to charge the fee as set forth in § 1.17(p) to the undersigned's credit card. The United States Patent and Trademark Office is authorized to charge any deficiency or credit any refund to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

By



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